

### **REMARKS**

With this amendment, claims 1-10, 13-21, and 24-28 remain pending in the application. Claims 1 and 14 have been amended to eliminate the word of “about”. With these amendments, the rejections to the pending claims are believed to have been addressed. Withdrawal of the rejection as to these claims is therefore requested.

In the Office Action of January 18, 2007 (Paper No. 20070107), claims 1 and 14 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 1-7, 9, 10, 13-18, 20 and 21 remain rejected under 35 U.S.C. §103(a) over Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620). Lastly, claims 8, 19 and 25-28 remain rejected under 35 U.S.C. §103(a) over Trese et al. as detailed above further in view of Trese et al. (American Academy of Ophthalmology, ISSN 1607-1610).

#### **Remarks Directed to Rejection under 35 USC § 112, First Paragraph**

Claims 1 and 14 are rejected under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement. The basis for the rejection, as stated on page 2 of the Paper “20070107”, is that “the range ... ‘less than 0.4 to about .01 units’ .... fails to set the lower limit .... The range could be less than .01 units, which is not expressly, implicitly or inherently disclosed in the specification.”

Applicant submits that claims 1 and 14 in current forms do comply with the written description requirement for the reasons stated as below.

The written description inquiry is a factual one and must be assessed on a case-by-case basis. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1116 (Fed.Cir.1991) As acknowledged on page 2 of the Paper, it is well-settled that the disclosure as originally filed

does not have to provide literal or “in haec verba” support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996).

Alternatively, as stated on page 2 of the Paper, Doctrine of Inherency may be applied as a means of satisfying the written description requirement. As such, the written description requirement is satisfied if the specification is so worded that “a person skilled in the relevant art...would not have to undertake any independent experimentation in order to find the missing discussion ‘inherent in the disclosures’...” *Sulfur-Tech Water Systems, Inc. v. Larry Kohlenberg et al.*, 162 F. Supp. 2d 743, 2001.

As to the present invention, an applicable dosage of plasmin is a relative term; the exact dosage of plasmin varies from subject to subject and depends on multiple factors (page 5, lines 1-4 of the specification). These multiple factors include the route of administration (page 4, lines 10-13 of the specification), the degree of temperature applied to the plasmin treatment (page 4, lines 13-14 of the specification), and volume and viscosity of the subject’s vitreous body (page 5, lines 1-4 of the specification).

Additionally, the applicable dosage of plasmin may further be varied when a plasmin inhibitor is also administered. As stated in the Specification, the plasmin inhibitor functions to inhibit plasmin activity in liquifying the vitreous body (page 7, lines 13-16). It follows in the minds of one skilled in the art that the effect of a particular plasmin dosage is inevitably modifiable by the use of a plasmin inhibitor.

Therefore, a disclosed range of 0.01-5 units of plasmin administration is only to be understood in the minds of one skilled in the art as a relative term. Without having to undertake any independent experimentation, one skilled in the art is capable of conceiving from the disclosure of the present invention that a dose of X units of plasmin as applied to an adult patient

with ample volume of vitreous body may be equivalent to a dose of X-Y units of plasmin as applied to a pediatric patient whose volume of vitreous body is much smaller. Similarly, a requirement of X (e.g. 0.01) units of plasmin with the use of a plasmin inhibitor may be decreased to one of X-Y units when the plasmin inhibitor is not in use.

Furthermore, it should be noted that an invention is not limited by the description thereof with reference to preferred embodiments, but rather the invention should be understood in the light of various adaptations and modifications as within the spirit and scope of the invention. *Sulfur-Tech Water Systems, Inc.*

As to the present invention, the disclosed range of 0.01-5 units as stated on page 5 of the specification is only provided as an embodiment as indicated by the use of "in general" (page 5, lines 7-8 of the specification). Therefore, Applicant submits that the present invention is not bound by the disclose dosage of 0.01 and 0.01 is not a practical lower limit.

Given then that the relevant inquiry is dependent on a consideration of a person of ordinary skill in the art, Applicant has clarified claims 1 and 14 to recite a lower limit of "0.01 units" for the recited range.

Therefore, reconsideration and withdrawal of the claims 1 and 14 under 35 U.S.C. 112, first paragraph is requested.

**Regarding the Rejection of Claims 1-7, 9, 10, 13-18, 20, 21 and 24 Under 35 U.S.C.  
§103(a) as Obvious Over Trese et al. (Ophthalmology)**

Applicant hereby incorporates by reference the remarks set forth in the prior Appeal Brief with respect to independent claim 1, independent claim 14 and Trese et al. (Ophthalmology).

**Regarding the Rejection of Claims 8, 19 and 25-28 Under 35 U.S.C. §103(a) as Obvious Over Trese et al. (Ophthalmology) and Further in View of Trese et al. (American).**

Applicant incorporates by reference the remarks set forth in the prior Appeal Brief with regard to Trese et al. (Ophthalmology).

**Summary**

Entry of this amendment is requested. With the entry of this amendment claims 1-10, 13-21 and 24-28 are pending in the application. Reconsideration and allowance of the pending claims is respectfully requested. In the event that the Examiner finds to the contrary, he is respectfully requested to contact the undersigned attorney to resolve any remaining issues.

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Respectfully submitted,

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